



08/8/2168

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for Extension of
Patent Term for patent of

: Mail Stop: Patent Extension

Shigenori OHKAWA et al.

: Legal Advisor Kathleen K. Fonda

Patent No. 6,034,239

: Attorney Docket No. 2006_2198

Issued March 7, 2000

:

Tricyclic Compounds, Their Production and Use

REPLY TO PTO DECISION ON RECONSIDERATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Reply to the PTO Decision on Reconsideration of the U. S. Patent and Trademark Office (PTO) dated January 31, 2008.

Applicant expresses its sincere thanks for the courtesy and consideration by the PTO of the Applicant's Petition.

Enclosed please find page 5 of Exhibit C as suggested in the PTO decision.

In view of the foregoing, it is believed that the Petition is now in condition for grant, and such action is kindly solicited.

Respectfully submitted,

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By

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1. Elucidation of Structure

Ramelteon is an indan derivative, with one asymmetric carbon at the 1-position of the indan backbone. The compound is produced selectively as the (*S*)-enantiomeric form. In addition to expectations that the established synthetic route will produce a compound having the claimed structure, the chemical structure of ramelteon was also confirmed by elemental analysis, various spectral analyses (UV, IR, NMR and MS) and an X-ray structural study. Further evidence for the claimed structure of ramelteon is provided by characterization studies that were performed for the key intermediate, (*S*)-AMI-HCl, which are described in Report M-11-00744 located later in this section.

Ramelteon lots M375-S02 (used for all studies except the X-ray structural study) and M375-S03 (used for X-ray structural study), each having a purity of 99.8%, were used for the characterization studies described in this section. The data from the studies establish the structure of ramelteon shown in Figure 1. Analytical results for the reference standard lot are found in Tables 1 and 2.

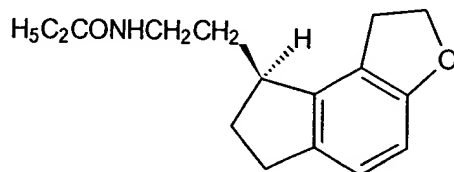


Figure 1 Structure of Ramelteon